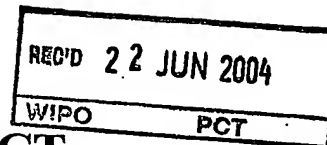


PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY



PCT

To:

Madderns
1st Floor Wolf Blass House
64 Hindmarsh Square
ADELAIDE SA 5000

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) **17 JUN 2004**

Applicant's or agent's file reference
23946PCT

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/AU2004/000403

International filing date (day/month/year)
31 March 2004

Priority date (day/month/year)
31 March 2003

International Patent Classification (IPC) or both national classification and IPC
Int. Cl. ⁷ G01N 33/68, 33/551, 33/546, 33/533, C12N 1/00

Applicant
WOMEN'S AND CHILDREN'S HOSPITAL et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU
**AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaaustralia.gov.au
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Authorized Officer
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2004/000403

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2004/000403

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 2 - 73	YES
	Claims 1	NO
Inventive step (IS)	Claims 2 - 73	YES
	Claims 1	NO
Industrial applicability (IA)	Claims 1 - 73	YES
	Claims	NO

2. Citations and explanations:

Novelty (N) and Inventive Step (IS)

AU 26869/97 (714818 B) by the same applicant discloses the features of claim 1 of a composition for screening for lysosomal storage disorders including the protein profiling method and the composition for diagnosis, the capture antibody capable of binding the target antigen, the conjugated microsphere as a fluorophore, the target antigen and LSD associated biomolecule. These features from the claims 2 to 73 are not disclosed in the citation, as the claims are currently drafted.

US 5501957 (DENNIS, J.W. et al) and The Journal of Clinical Investigation (Feb 1986), 77(2), pp568-74 serve as background material.

Industrial Applicability (IA)

No issues of lack of industrial applicability arise.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/000403

A. CLASSIFICATION OF SUBJECT MATTER		
Int. Cl. ⁷ : G01N 33/68, 33/551, 33/546, 33/533, C12N 1/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched IPC AS ABOVE		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI and IPC as above, keywords (lysosome, microsphere, antibody, fluorophore, fluorescence, LSD, lysosomal storage disorder, multiplex and like terms)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	AU 26869/97 (714818 B) (WOMEN'S AND CHILDREN'S HOSPITAL) 17 May 1997 See whole specification	1
A	US 5501957 B (DENNIS, J.W. et al) 26 March 1996 See whole specification	1 - 73
A	The Journal of Clinical Investigation (Feb 1986), 77(2), pp568-74 See abstract and discussion page 572	1 - 73
<input type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>		
Date of the actual completion of the international search 9 June 2004		Date of mailing of the international search report 17 JUN 2004
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929		Authorized officer ANTHEA HARVIE Telephone No : (02) 6283 2552

Form PCT/ISA/210 (second sheet) (January 2004)

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